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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,680	01/04/2002	James R. Ellsworth	70869-0074US	1027

7590

11/12/2003

Conrad J Clark
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Washington, DC 20006

EXAMINER

SORKIN, DAVID L

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,680

Applicant(s)

ELLSWORTH ET AL.

Examiner

David L. Sorkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 04/25/03. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10, in a response filed 29 September 2003 is acknowledged.

Claim Rejections - 35 USC § 112

2. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. As amended, claim 1 recites "a central portion extending across at least a portion of said cavity and having an upper surface, said central portion being configured such that after centrifugation of blood said upper surface lies just below the top of a layer of separated red blood cells". In the same vein, amended claim 10 recites, "said central portion lies just below an interface between plasma and red blood cells". The specification discusses the "central portion" on page 6, lines 12-20. The "central portion" is referred to as "22" and depicted in Fig. 4. It is clear from the specification and drawings that the "central portion" extends above the top of the red blood cell layer. The upper surface of the central portion is clearly above the red blood cell layer. Instead of what is recited in the instant claims, the specification states that "the concave surface 20 is just below the interface" (page 6, lines 15-16).

Claim Rejections - 35 USC §§ 102 and 103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayres (US 3,909,419). Regarding claims 1 and 10, Ayres ('419) discloses, in combination, a tube (11) comprising an inner wall forming a cavity adapted to contain a fluid to be subjected to centrifugation (see col. 2, lines 38-42) and a separator disc (16) in said tube adapted to separate components of said fluid having different specific gravities, said disc being made of a material having a specific gravity near the specific gravity of red blood cells (see col. 2, lines 21-28) and comprising a peripheral portion adjacent said inner wall of said tube and a central portion extending across at least a portion of said cavity and having an upper surface (see Fig. 1), said central portion being configured such that after centrifugation of blood and upper surface lies just below the top layer of separated red blood cells (see col. 2, lines 21-28 and 38-52). Regarding claim 4, said disk is arranged to rotate about an axis transverse to the longitudinal axis

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of said tube (see Fig. 1). Regarding claims 7 and 8, the upper surface is curved and cylindrical (see col. 2, line 24).

6. Claims 1, 2, 4, 6-8 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levine (US 5,707,876). Regarding claims 1 and 10, Ayres ('419) discloses, in combination, a tube (4) comprising an inner wall forming a cavity adapted to contain a fluid to be subjected to centrifugation (see col. 4, lines 1-2) and a separator disc (one of 14,16,18, etc.) in said tube adapted to separate components of said fluid having different specific gravities, said disc being made of a material having a specific gravity near the specific gravity of red blood cells (see col. 2, lines 1-10) and comprising a peripheral portion adjacent said inner wall of said tube and a central portion extending across at least a portion of said cavity and having an upper surface (see Fig. 2). It is considered that col. 2, line 1-10 would have disclosed or suggested to one of ordinary skill in the art that said central portion being configured such that after centrifugation of blood and upper surface lies just below the top layer of separated red blood cells. Regarding claim 2, said disk fits into said tube such that a gap is formed between the perimeter of said disk and the interior of said tube, said gap being of such dimension that the component of said below said disk after separation will not flow through said gap at about 1G (see col. 6, lines 1-4). Regarding claim 4, said disk is arranged to rotate about an axis transverse to the longitudinal axis of said tube (see Fig. 2). Regarding claim 6, as held in *Gardner v. TEC Systems, Inc.* 220 USPQ 777 (Fed. Cir. 1984), if the only difference between the prior art and the claims is a recitation of relative dimensions, the claimed device is not

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patentably distinct from the prior art unless a device having the claimed dimension would perform differently. Regarding claims 7 and 8, the upper surface is curved and cylindrical (see Fig. 2).

Response to Arguments

7. Applicant's arguments have been considered but are moot in view of the new grounds of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

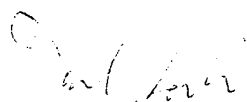
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David Sorkin



**CHARLES E. COOLEY
PRIMARY EXAMINER**